

EXHIBIT “B”

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.
2. The following documents for the design and development of Project Scion, TVT-PA and TTVT+M, including but not limited to:
 - a. The Clinical Expert reports;
 - b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);
 - c. Operating Procedures for Failure Modes and Effects Analysis;
 - d. Operating Procedure for Device Design Safety Assessment;
 - e. Design history files;
 - f. Design and specifications of equipment used in the production of Project Scion, TTVT-PA and TTVT+M;
 - g. Design and specifications of packaging used in the production of Project Scion, TTVT-PA and TTVT+M;
 - h. Specifications regarding sanitization and sterilization of Project Scion, TTVT-PA and TTVT+M, plant facilities and plant equipment;
 - i. Mesh Specifications;
 - j. Franchise procedure for medical device risk management plan;
 - k. Company procedure for medical device risk management plan;
 - l. Work Instruction for device risk management;
 - m. The Franchise procedure for the control and disposition of nonconforming product;
 - n. All company policies and procedures that apply to or relate to the Design History File;

- o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;
 - p. Risk management plans and reports for Project Scion, TVT-PA and TTVT+M;
 - q. Members of product development team(s);
 - r. Operating procedures associated with a product development cycle;
 - s. Project Scion, TTVT-PA and TTVT+M quality manual;
 - t. Project Scion, TTVT-PA and TTVT+M quality plan;
 - u. Management responsibilities under a quality system;
 - v. Mesh product design review, design verification, process qualification and design transfer;
 - w. Mesh product device design requirements matrix;
 - x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;
 - y. Mesh product validation test reports; and
 - z. Mesh product biocompatibility testing records;
3. Testing and validation of Project Scion, TTVT-PA and TTVT+M.